

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
18 March 2004 (18.03.2004)

PCT

(10) International Publication Number  
**WO 2004/022117 A1**

(51) International Patent Classification<sup>7</sup>: **A61L 15/42**

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(21) International Application Number:  
PCT/US2003/025643

(22) International Filing Date: 15 August 2003 (15.08.2003)

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(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
10/238,106 9 September 2002 (09.09.2002) US

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

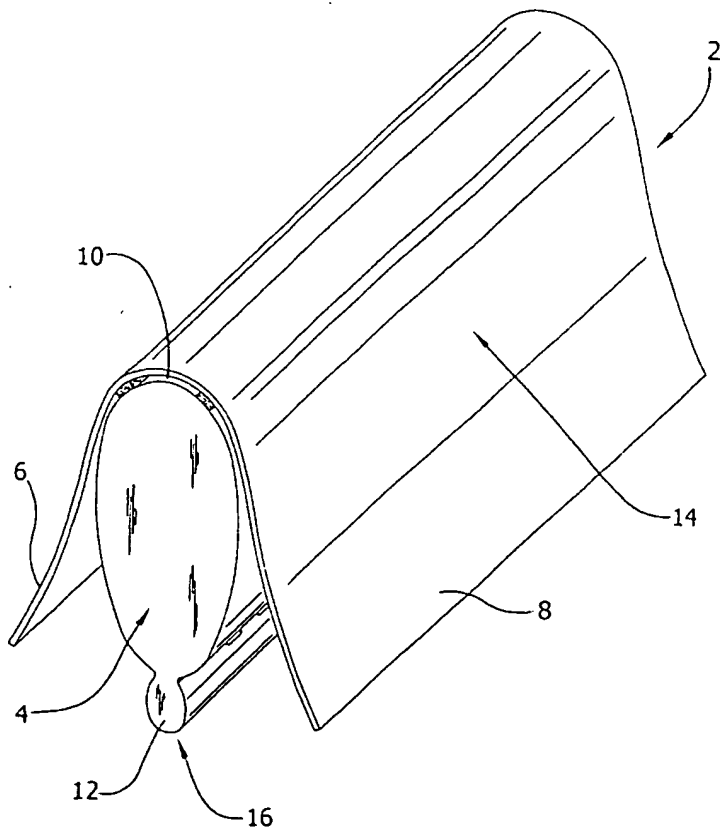
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(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,

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[Continued on next page]

(54) Title: MOISTURIZING AND LUBRICATING COMPOSITION



(57) Abstract: The present invention is generally directed to moisturizing and lubricating compositions for use on the bodyfacing surface of an absorbent product such as an interlabial pad. The moisturizing and lubricating compositions comprise an emollient, a humectant, and an immobilizing agent. Optionally, the moisturizing and lubricating compositions can comprise a skin barrier enhancing agent such as a fat or oil and an antioxidant, and/or a sterol or sterol derivative.



ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,  
SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM,  
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— *before the expiration of the time limit for amending the  
claims and to be republished in the event of receipt of  
amendments*

**Published:**

— *with international search report*

*For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.*

## MOISTURIZING AND LUBRICATING COMPOSITION

BACKGROUND OF THE INVENTION

This invention is directed to moisturizing and lubricating compositions which may be used on absorbent products such as interlabial pads and/or interlabial devices. More particularly, this invention is directed towards moisturizing and lubricating compositions for use on the bodyfacing surface of an absorbent product, such as an interlabial pad, which improve the level of comfort to the wearer and may provide a skin health benefit.

Feminine protection devices such as tampons and sanitary napkins are well-known in the art for receiving and absorbing menses and other vaginal discharges. Tampons are used internally within the vaginal cavity for receiving menstrual flow therefrom, while sanitary napkins are worn externally and receive menses externally from the vagina. Because tampons and sanitary napkins each have known drawbacks, recently interlabial pads, which are hybrid devices based on tampons and sanitary napkins, have been developed.

Interlabial pads and/or devices may provide a satisfactory alternative to tampons and sanitary napkins due to their convenient small size and good absorbency characteristics which reduce the chance of leakage. Despite these advantages, to date interlabial pads have met with only limited success. The primary reason for the limited commercial success appears to be issues related to the comfort level provided to the wearer of the product. Specifically, some interlabial pads have been found uncomfortable to wear due to frictional discomfort associated with the rubbing of the product against the labial walls and sticking of the surfaces of the device to the labial walls. Additionally, the sticking of the bodyside surface of the interlabial pad to the labia can prevent the interlabial device from being inserted properly which may lead to comfort issues as well. Further, the interlabial device, upon

initial insertion, may pull away and absorb the natural moisture from the interlabial mucous membranes which may lead to an uncomfortable, dry feeling.

The drying of the interlabial walls and the sticking of the interlabial pad to the walls is believed to be caused by a drying of the interlabial area during wear of the interlabial product which can lead to friction and the sticking of the pad onto the interlabial walls of the wearer. U.S. Patent No. 5,981,126 (Osborn, III et al.) discloses absorbent devices to be worn interlabially by female wearers that have a hydrophobic emollient composition on the bodyfacing surface to prevent drying of the labial tissue and reduce friction during wear. The hydrophobic emollient composition may comprise an emollient, an immobilizing agent and optionally a hydrophilic surfactant and/or other ingredients such as viscosity modifiers and pH modifiers. A suitable emollient composition is set forth in Example 1 and comprises mineral oil, cetearyl alcohol, steareth-2, and phenyl trimethicone.

U.S. Patent No. 5,869,075 (Krzysik) discloses a soft tissue product such as a facial tissue, bath tissue, or paper towel which is constructed by applying a melted hydrophilic composition to the surface of the product and allowing it to re-solidify. The composition has a melting point from about 30°C to about 70°C and a penetration hardness of from about 5 millimeters to about 360 millimeters and may comprise a hydrophilic solvent, polyethylene glycol, and a fatty alcohol. A suitable formulation for the composition is set forth in Example 6 and comprises propylene glycol, a combination of fatty acids, hydrogenated starch hydrolysate, Hispagel 200, Lubrasil, Ostar Arriveen PG25, dimethicone and myristyl myristate.

Although there has been some improvement in the wearability of interlabial pads and devices through the use of lubricating compositions, a need continues to exist for improved interlabial pads which can be comfortably worn for

extended periods of time. Specifically, a need continues to exist for lubricating and moisturizing compositions which are suitable for use on interlabial pads and will provide for improved wearability of the pads, along with improving the health of the skin.

#### SUMMARY OF THE INVENTION

The present invention is generally directed to moisturizing and lubricating compositions for use in combination with absorbent products such as interlabial pads. The moisturizing and lubricating compositions, which are preferably hydrophilic, are introduced onto the bodyfacing surface of the interlabial pad such that during insertion and wear of the pad, the composition contacts the labial area and is at least partially transferred onto the labial area to improve the comfort level of the interlabial pad.

In one embodiment described herein, at least a portion of the bodyfacing surface of the interlabial pad comprises a hydrophilic composition which is solid or semisolid at a temperature of about 30°C to about 80°C and comprises a humectant, and emollient, and an immobilizing agent. A preferred moisturizing and lubricating composition comprises a high molecular weight polyethylene glycol, glycerin, a fatty alcohol, a silicone, and propylene glycol. Optionally, the moisturizing and lubricating compositions of the present invention may comprise a skin barrier enhancing agent, such as sunflower oil or borage oil, and an antioxidant to stabilize the skin barrier enhancing agent. Additionally, a sterol or sterol derivative may be added to improve skin health.

The moisturizing and lubricating compositions of the present invention provide a reduction in the frictional discomfort associated with the rubbing of the interlabial pad against the labial walls. Additionally, the moisturizing and lubricating compositions of the present invention decrease the amount of sticking of the interlabial pad to the labial

walls. These benefits allow the interlabial pad to be inserted into the labial area more easily and comfortably, and allow the interlabial pad to be worn comfortably for extended periods of time.

5

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an interlabial pad which could be used in combination with the moisturizing and lubricating composition of the present invention.

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#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In accordance with the present invention, it has been discovered that the bodyfacing surface of absorbent products can be treated with a moisturizing and lubricating composition to improve the overall performance of the absorbent product. In particular, interlabial pads can be worn comfortably for extended periods of time with a reduced amount of friction and drying of the labial area when a composition comprising a humectant, an emollient, and a stabilizing agent is introduced onto at least a part of the bodyfacing surface of the interlabial pad. Surprisingly, it has also been discovered that a skin barrier enhancing agent such as a fat or oil can be included in the composition to improve the health of the skin in the labial area when used in combination with an antioxidant to stabilize the skin barrier enhancing agent and improve its shelf life. In a preferred embodiment, the moisturizing and lubricating compositions are hydrophilic.

The moisturizing and lubricating compositions of the present invention are suitable for use on the bodyfacing surface of numerous absorbent products which contact the skin and/or vaginal/labial areas during use. Although the present invention is primarily described herein in relation to an interlabial pad, it should be recognized that the moisturizing and lubricating compositions are suitable for use on the bodyfacing surface of numerous other absorbent

products such as tampons, sanitary napkins and pads, pantyliners, diapers, adult incontinence garments and the like.

One embodiment of the present invention is directed  
5 towards an interlabial absorbent pad which has a bodyfacing surface comprising a moisturizing and lubricating composition described below. At least a portion of the bodyfacing surface is coated with the moisturizing and lubricating composition to prevent drying of the labial area during wear  
10 and improve the overall comfort level of the wearer while reducing friction. Interlabial pads, also commonly referred to as interlabial devices, are commonly known in the art and refer to a structure that has absorbent components and is configured to reside at least partially, and in some  
15 embodiments completely, within the interlabial space of a female wearer during use to absorb menses, other vaginal discharges, and/or urine. Interlabial pads such as those described in U.S. Patent No. 5,891,126 and U.S. Patent Application No. 2002/0058921 are exemplary interlabial pads  
20 suitable for use with the moisturizing and lubricating compositions of the present invention.

By way of a brief illustration of a conventional interlabial pad and now referring to Figure 1, there is shown an interlabial pad 2 comprising a main absorbent portion 4  
25 and a pair of flexible extensions 6 and 8 joined to the main absorbent portion 4. The main absorbent portion 4 is at least partially, and preferably substantially, suitable for absorbing bodily fluids. The main absorbent portion 4 may comprise non-absorbent portions, such as a liquid impervious  
30 barrier to prevent absorbed exudates, such as menses, from leaking out of the main absorbent portion 4. The main absorbent portion 4 comprises an upper portion 10 and lower portion 12 that is opposed the upper portion 10. In use, the upper portion 10 is positioned furthest inward into the  
35 wearer's interlabial space. The interlabial pad 2 has a bodyfacing surface 14 and a back surface 16. The bodyfacing

surface 14 is the surface to which the moisturizing and lubricating compositions of the present invention are applied such that during use of the interlabial pad, the moisturizing and lubricating composition is in intimate contact with the labial area and can be, at least in part, transferred to the labial area to provide one or more of the benefits described herein.

The bodyfacing surface is made of a material which is flexible and non-irritating to the tissues with the labial area of the wearer. As used herein, the term "flexible" is intended to refer to materials which are compliant and readily conform to the bodily surface(s) with which such materials are in contact, or materials which respond by easily deforming in the presence of external forces. The bodyfacing surface may be constructed of any woven or nonwoven material which is easily penetrated by bodily fluids which contact the surface. Examples of suitable materials include rayon, spunlace, bonded carded webs of polyester, polypropylene, polyethylene, nylon, or other heat-bondable or starch-bondable fibers, polyolefins, such as copolymers of polypropylene and polyethylene, linear low-density polyethylene, and aliphatic esters such as polylactic acid. Finely perforated film webs and net material can also be used. A specific example of a suitable cover material is a bonded carded web made of polypropylene and polyethylene such as that used as cover stock for KOTEX pantliners and obtainable from Sandler Corporation (Germany). Other examples of suitable materials are composite materials of polymer and nonwoven fabric materials. The composite materials are typically in the form of integral sheets generally formed by the extrusion of a polymer onto a web of spunbonded material.

The interlabial pad 2 should be of a suitable size and shape that allows at least a portion of the interlabial pad to fit comfortably within the wearer's interlabial space and to cover the wearer's vaginal orifice, and preferably also



the wearer's urethra. The interlabial pad 2 at least partially blocks, and more preferably completely blocks and intercepts the flow of menses, urine, and other bodily exudates from the wearer's vaginal orifice and urethra.

5 Preferably, the bodyfacing surface 14 fits snugly against the labial walls to allow contact between the moisturizing and lubricating compositions of the present invention and the labial walls.

10 The moisturizing and lubricating compositions of the present invention are preferably hydrophilic in nature; that is, the compositions are attracted to, and retain, water. It has been discovered that hydrophilic moisturizing and lubricating compositions for use on the bodyfacing surface of absorbent products such as an interlabial pad typically  
15 introduce a higher level of moisture onto the skin or mucosal area, and retain the moisture in that area, as compared to hydrophobic compositions. As such, in accordance with the present invention, it is preferred that the moisturizing and lubricating compositions of the present invention be  
20 hydrophilic in nature. One measurement of a composition's hydrophilicity is the composition's ability to dissolve in water. Typically, such dissolution evaluations are done with heated water to improve the rate of dissolution. The more soluble a composition is in water (typically compositions may  
25 be tested with water at a temperature of about 80°C as the formulations may be solid at room temperature) the more hydrophilic the composition. As such, it is preferred that the moisturizing and lubricating compositions of the present invention have a high degree of solubility in heated water.

30 More specifically, the lubricating and moisturizing compositions of the present invention are preferably at least about 40%, more preferably at least about 45%, more preferably at least about 60%, more preferably at least about 70%, and still more preferably at least about 80% soluble in  
35 deionized water at a temperature of about 80°C. A preferred moisturizing and lubricating composition of the present

invention is about 80% soluble in deionized water at a temperature of about 80°C. At these levels of solubility in 80°C deionized water, the moisturizing and lubricating compositions of the present invention are sufficiently hydrophilic to provide the intended benefits.

The lubricating and moisturizing compositions of the present invention which are introduced onto the bodyfacing surface of the interlabial pad preferably have a melting point of from about 30°C to about 80°C, and more preferably from about 55°C to about 65°C. A preferred melting point for the moisturizing and lubricating compositions of the present invention is from about 60°C to about 62°C. With melting points in these ranges, and especially in the 55°C to 65°C range, the moisturizing and lubricating compositions of the present invention have a reduced tendency to flow easily and migrate into the interior of the absorbent product to which they are applied to the product and utilized by the wearer. This is important for at least two reasons. First, it is preferred that the majority of the moisturizing and lubricating composition remain on the surface of the absorbent product to allow direct interaction with the skin or mucous membrane it contacts. As such, a sufficiently high melting temperature is desired such that the moisturizing and lubricating composition freezes, or solidifies, onto the substrate to which it is applied in a short amount of time to reduce the potential for run-off or migration. Therefore, it is preferred that the moisturizing and lubricating composition freeze onto the substrate in no more than about 0.25 seconds, preferably no more than about 3 seconds. With freezing rates in these ranges, the moisturizing and lubricating compositions of the present invention solidify quickly onto the substrate and the potential for migration is minimized.

Secondly, the melting point needs to be sufficiently high to provide sufficient stability for the composition. Stated another way, the melting points are desirably higher

than the temperatures that the product to which the moisturizing and lubrication has been applied is exposed to during storage and transport, which may be as high as about 55°C.

5        Additionally, the moisturizing and lubricating compositions of the present invention preferably have a penetration hardness (needle penetration in millimeters according to ASTM D 1321, "Needle Penetration of Petroleum Waxes") of from about 5 millimeters to about 360 millimeters,  
10        preferably from about 10 millimeters to about 120 millimeters, and most preferably from about 20 millimeters to about 100 millimeters. Penetration hardness of the moisturizing and lubricating compositions of the present invention may be important for two reasons. First, the  
15        softer the formulation (i.e., the higher the penetration hardness number) the more mobile the formulation will be, making the formulation more likely to migrate into the inner layers of the absorbent product, which is typically not desirable, especially in interlabial pads. As such, it is  
20        typically desirable to have a penetration hardness of at least about 5 millimeters and more preferably at least about 40 millimeters to reduce this likelihood.

      Second, very soft formulations tend to be more greasy/oily to the touch, which is typically not desirable on  
25        most absorbent products. By requiring the moisturizing and lubricating compositions of the present invention to have a penetration hardness as described above, these compositions are less likely to migrate yet maintain a silky, creamy feeling on the surface of an absorbent product.

30        Additionally, in absorbent products such as interlabial pads, there is typically less concern with actually transferring a substantial amount of the moisturizing and lubricating composition to the labial area. Although a smaller amount of transfer may be desirable to improve moisturization and  
35        lubrication, harder formulations are typically preferred

because significant transfer is not as important as a soft, cream feel.

Many of the moisturizing and lubricating compositions described herein contain a sufficient amount of a humectant component to allow the composition to absorb and hold a significant amount of water. Typically, it is preferred that the moisturizing and lubricating compositions of the present invention have sufficient water vapor absorptivity (water pickup) to allow the composition to sufficiently moisturize the skin from vapor absorbed.

The moisturizing and lubricating compositions of the present invention are preferably substantially non-irritating to the skin or mucous membrane to which they contact during use by the wearer; that is, it is preferred that the moisturizing and lubricating compositions not induce redness and/or swelling of the skin tissues when contacted with the skin of the wearer. Further, it is preferred that the moisturizing and lubricating compositions not interfere with or hinder the natural ability of the skin and mucous membranes to repair themselves from injury due to, for example, wiping or other abrasive activity. As discussed below, some of the moisturizing and lubricating compositions of the present invention may contain a fat or oil and/or a sterol or sterol derivative to facilitate repair of the skin from such damage.

The moisturizing and lubricating compositions of the present invention comprise an emollient, a humectant, an immobilizing agent, and optionally a skin barrier enhancing agent and an antioxidant. Other optional components may also be included in the moisturizing and lubricating compositions described herein.

The moisturizing and lubricating compositions of the present invention comprise from about 0% (by weight) to about 25% (by weight) emollients, more preferably from about 1% (by weight) to about 25% (by weight). As used herein, the term "by weight" refers to the total weight of the moisturizing

and lubricating composition. Thus, if a moisturizing and lubricating composition is 25% (by weight) emollients and has a total weight of 100 grams, the compositions comprises 25 grams of emollient. As used herein, an emollient refers to a compound that smoothes, softens, soothes, supples, coats, lubricates, moisturizes, protects and/or cleanses the skin and/or mucous membranes, such as labial walls, upon contact.

Emollients suitable for use in the moisturizing and lubricating compositions of the present invention include, but are not limited to, petroleum based emollients, fatty acids esters, alkyl ethoxylates, fatty alcohols and silicones such as dimethicone, dimethiconol, PEG dimethicone, alkyl silicones, phenyl silicones, and silicone phospholipids, and combinations thereof.

Suitable petroleum based emollients include those hydrocarbons, or mixtures of hydrocarbons, having chain lengths of from 16 to 32 carbon atoms. Petroleum based hydrocarbons having these chain lengths include mineral oil (also known as "liquid petrolatum") and petrolatum (also known as "mineral wax," petroleum jelly" and "mineral jelly"). Mineral oil usually refers to less viscous mixtures of hydrocarbons having from 16 to 20 carbon atoms. Petrolatum usually refers to more viscous mixtures of hydrocarbons having from 16 to 32 carbon atoms.

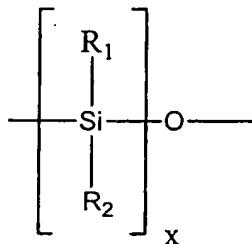
Suitable fatty acid ester emollients include those derived from  $C_{12}$ - $C_{28}$  fatty acids, preferably  $C_{16}$ - $C_{22}$  saturated fatty acids, and short chain, such as  $C_1$ - $C_8$ , preferably  $C_1$ - $C_3$ , monohydric alcohols. Examples include methyl palmitate, methyl stearate, isopropyl laurate, isopropyl myristate, butyl myristate, butyl stearate, octyl palmitate, isopropyl isostearate, isopropyl palmitate, ethylhexyl palmitate, and mixtures thereof. Suitable fatty acid ester emollients can also be derived from monoesters and diesters of both short chain, such as  $C_1$ - $C_{10}$ , and longer chain fatty alcohols, such as  $C_{12}$ - $C_{28}$ , preferably  $C_{12}$ - $C_{16}$ , and shorter chain organic acids such as lactic acid, lauryl lactate and cetyl lactate.

Additional examples include diisopropyl sebacate, dimethyl sebacate, dioctyl sebacate, dibutyl sebacate, diisopropyl adipate, and dicapryl adipate. In addition, mixtures of petroleum based emollients and fatty acid ester emollients can provide emollient systems that have a superior feel compared to the pure components individually.

Suitable alkyl ethoxylate type emollients include  $C_{12}$ - $C_{22}$  fatty alcohol ethoxylates having an average degree of ethoxylation of from about 2 to about 30. Preferably, the fatty alcohol ethoxylate emollient is selected from the group of lauryl, cetyl, and stearyl ethoxylates, and mixtures thereof, having an average degree of ethoxylation ranging from about 2 to about 23. Representative examples of such alkyl ethoxylates include laureth-3 (a lauryl ethoxylate having an average degree of ethoxylation of 3), laureth-23 (a lauryl ethoxylate having an average degree of ethoxylation of 23), ceteth-10 (a cetyl alcohol ethoxylate having an average degree of ethoxylation of 10) steareth -10 (a stearyl alcohol ethoxylate having an average degree of ethoxylation of 10), and cetareth-10 ( a mixture of cetyl and stearyl ethoxylates having an average degree of ethoxylation of 10). Additionally, alkyl ethoxylates with an HLB of from about 2 to about 7 are also useful as emulsifiers or compatibilizers/solubilizers of other emollients in the composition.

Suitable fatty alcohol-type emollients include alcohols having a carbon chain length of  $C_{14}$ - $C_{30}$ , including cetyl alcohol, stearyl alcohol, arachidyl alcohol, and behenyl alcohol and mixtures thereof. Additionally,  $C_9$ - $C_{15}$  alcohols including caprylic alcohol, cetearyl alcohol, coconut alcohol, decyl alcohol, hydrogenated tallow alcohol, lanolin alcohol, lauryl alcohol, myristyl alcohol, oleyl alcohol, palm alcohol, palm kernel alcohol, tallow alcohol, tridcyl alcohol and like are suitable fatty alcohol-type emollients.

Another suitable type of emollient is a polysiloxane compound. Generally, suitable polysiloxane materials for use include those having monomeric siloxane units having the following structure:



5 wherein x is a whole number from 1 to about 1,000,000 and R<sub>1</sub> and R<sub>2</sub> for each independent siloxane monomeric unit can each independently be hydrogen or any alkyl, aryl, alkenyl, alkaryl, arakyl, cycloalkyl, halogenated hydrocarbon, or other radical. Any of such radicals can be substituted or  
 10 unsubstituted. R<sub>1</sub> and R<sub>2</sub> radicals of any particular monomeric unit may differ from the corresponding functionalities of the next adjoining monomeric unit. Additionally, the polysiloxane can be either a straight chain, a branched chain or have a cyclic structure. The radicals R<sub>1</sub> and R<sub>2</sub> can  
 15 additionally independently be other silaceous functionalities such as, but not limited to siloxanes, polysiloxanes, silanes, and polysilanes. The radicals R<sub>1</sub> and R<sub>2</sub> may contain a variety of organic functionalities including, for example, alcohol, carboxylic acid, phenyl, and amine functionalities.

20 Exemplary radicals are methyl, ethyl, propyl, butyl, pentyl, hexyl, octyl, decyl, octadecyl, and the like. Exemplary alkenyl radicals are vinyl, allyl, and the like. Exemplary aryl radicals are phenyl, diphenyl, naphthyl, and the like. Exemplary alkaryl radicals are toyl, xylyl,  
 25 ethylphenyl, and the like. Exemplary aralkyl radicals are benzyl, alphaphenylethyl, beta-phenylethyl, alpha-phenylbutyl, and the like. Exemplary cycloalkyl radicals are cyclobutyl, cyclopentyl, cyclohexyl, and the like. Exemplary halogenated hydrocarbon radicals are chloromethyl,

halogenated hydrocarbon radicals are chloromethyl, bromoethyl, tetrafluorethyl, fluorethyl, trifluorethyl, trifluorotoyl, hexafluoroxylyl, and the like.

5 The viscosity of the useful polysiloxanes may vary widely. So long as the polysiloxane is flowable or can be made to be flowable for applications to the bodyfacing surface of the interlabial pad, the polysiloxane viscosity is acceptable. This includes, but is not limited to, viscosity as low as 5 centistokes (at 37°C as measured by a glass  
10 viscometer) to about 20,000,000 centistokes (at 37°C as measured by a glass viscometer). A preferred range is from about 5 centistokes to about 5,000 centistokes. In one embodiment, a mixture of a low viscosity dimethicone (about 5 centistokes to about 350 centistokes) and a high viscosity  
15 dimethicone or dimethiconol or silicone gum (1,000,000 centistokes to about 20,000,000 centistokes) is preferred as the mixture produces a pleasant feeling material and provides additional lubricity. Preferred ranges of the low viscosity polysiloxane to high viscosity polysiloxane is from about 1:1  
20 to about 10:1.

Preferred polysiloxane compounds for use as emollients in the present invention are disclosed in U.S. Patent No. 5,059,282 (Ampulski, et al.). Particularly preferred polysiloxane compounds for use as emollients in the  
25 moisturizing and lubricating compositions of the present invention include phenyl-functional polymethylsiloxane compounds (e.g., Dow Corning 556 Cosmetic-Grade Fluid) and cetyl or stearyl functionalized dimethicones such as Dow 2502, General Electric SF1632 and Dow 2503 polysiloxane  
30 fluids. In addition to such substitution with phenyl-functional or alkyl groups, effective substitution may be made with amino, carboxyl, hydroxyl, ether, polyether, aldehyde, ketone, amide, ester, and thiol groups. Phenyl, amino, alkyl, carboxyl, and hydroxyl groups are preferred,  
35 with phenyl functional groups being most preferred.



Cyclic polysiloxane structures can also be utilized as polysiloxane emollients. Examples of cyclic polysiloxane structures include cyclomethicones such as Dow Corning 244, Dow Corning 245, Dow Corning 344, and Dow Corning 345 fluids.

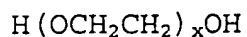
5 In addition, nonfunctionalized polysiloxane compounds can also be used herein as emollients.

The humectant component of the moisturizing and lubricating compositions of the present invention are generally present in an amount of from about 5% (by weight) to about 90% (by weight). Humectants are typically cosmetic ingredients used to increase the water content of the top layers of the skin or mucous membrane, by helping control the moisture exchange between the product, the skin, and the atmosphere. Humectants may include primarily hydroscopic materials. Suitable humectants for inclusion in the moisturizing and lubrication compositions of the present invention include N-Acetyl ethanolamine, aloe vera gel, arginine PCA, chitosan PCA, copper PCA, Corn glycerides, dimethyl imidazolidinone, fructose, glucamine, glucose, glucose glutamate, glucuronic acid, glutamic acid, glycereth-7, glycereth-12, glycereth-20, glycereth-26, glycerin, honey, hydrogenated honey, hydrogenated starch hydrolysates, hydrolyzed corn starch, lactamide MEA, lactic acid, lactose lysine PCA, mannitol, methyl gluceth-10, methyl gluceth-20, PCA, PEG-2 lactamide, PEG-10 propylene glycol, polyamino acids, polysaccharides, polyamino sugar condensate, potassium PCA, propylene glycol, propylene glycol citrate, saccharide hydrolysate, saccharide isomerate, sodium aspartate, sodium lactate, sodium PCA, sorbitol, TEA-lactate, TEA-PCA, Urea, Xylitol, and the like and mixtures thereof. Preferred humectants include polyols, glycerine, ethoxylated glycerine, polyethylene glycols, hydrogenated starch hydrolysates, propylene glycol, silicone glycol and pyrrolidone carboxylic acid.

35 The immobilizing agent component of the moisturizing and lubricating compositions of the present invention are

generally present in an amount of from about 10% (by weight) to about 90% (by weight). The immobilizing agent will reduce the tendency of the emollient and humectant to migrate or flow by keeping the emollient and humectant primarily localized on the bodyfacing surface of the interlabial device. In addition to immobilizing the emollient and humectant, the immobilizing agent may provide a slight tackiness to the moisturizing and lubricating composition which may improve transfer of the composition to skin or membrane of the wearer.

Suitable immobilizing agents for use with the moisturizing and lubricating compositions of the present invention include  $C_{14}$ - $C_{22}$  fatty alcohols,  $C_{12}$ - $C_{22}$  fatty acids, solid fatty acid esters,  $C_{12}$ - $C_{22}$  fatty alcohol ethoxylates having an average degree of ethoxylation ranging from about 2 to about 30, and high molecular weight polyethylene glycols (a polymer of ethylene oxides) having the following empirical formula:



wherein  $x$  is the degree of ethoxylation and is an average value of from about 18 to about 160,000. Preferably,  $x$  is an average value of from about 135 to about 45,000, and even more preferably from about 6000 to about 20,000.

Particularly preferred high molecular weight polyethylene glycols are polyethylene glycols having the technical names of PEG 6000 (where  $x = 6000$ ), PEG 8000 (where  $x = 8000$ ), PEG 10,000 (where  $x = 10,000$ ), PEG 14,000 (where  $x = 14,000$ ), and PEG 20,000 (where  $x = 20,000$ ).

Preferred fatty alcohol immobilizing agents include  $C_{16}$ - $C_{18}$  fatty alcohols such as cetyl alcohol, stearyl alcohol, behenyl alcohol, and mixtures thereof. The preferred immobilizing agents increase the rate of crystallization of the emollient causing the emollient to crystallize rapidly onto the bodyfacing surface of the interlabial pad.

In addition to the emollient, humectant, and immobilizing agent components, the moisturizing and lubricating compositions of the present invention may optionally include a skin barrier enhancing agent, such as a fat or oil (triglyceride/essential and non-essential fatty acid containing), to enhance the barrier function of the stratum corneum layer of the skin or mucous membrane. Skin and mucous membranes are comprised mainly of cholesterol, ceramides, and fatty acids. The addition of fats, oils, or triglycerides alone or in combination with sterols or sterol derivatives to the moisturizing and lubricating composition can refat/replenish or enhance the natural lipid barrier of the skin or mucous membranes that comes in contact with the cover of the absorbent product comprising the moisturizing and lubricating composition. In addition to reforming structures needed to provide the proper lipid structures in the skin, the natural fats and oils will not substantially negatively affect the natural skin barrier if repair is not necessary.

The skin barrier enhancing agent is typically from about 0.1% (by weight) to about 30% (by weight), more preferably from about 0.5% (by weight) to about 20% (by weight), and still more preferably from about 1% (by weight) to about 10% (by weight). Suitable fats or oils, or mixtures thereof, for inclusion in the moisturizing and lubricating compositions of the present invention typically comprise glycerides, triglycerides and/or essential and/or non-essential fatty acids. Suitable examples include apricot kernel oil, avocado oil, babassu oil, borage seed oil, butter, C<sub>12</sub>-C<sub>18</sub> acid triglyceride, camellia oil, canola oil, caprylic/capric/lauric triglyceride, caprylic/capric/linoleic triglyceride, caprylic/capric/stearic triglyceride, caprylic/capric triglyceride, carrot oil, cashew nut oil, castor oil, cherry pit oil, chia oil, cocoa butter, coconut oil, cod liver oil, corn germ oil, corn oil, cottonseed oil, C<sub>10</sub>-C<sub>18</sub> triglycerides, egg oil, epoxidized soybean oil,

evening primrose oil, glyceryl triacetyl hydroxystearate, glyceryl triacetyl ricinoleate, glycosphingolipids, grape seed oil, hazelnut oil, human placental lipids, hybrid safflower oil, hybrid sunflower seed oil, hydrogenated castor oil, hydrogenated castor oil laurate, hydrogenated coconut oil, hydrogenated cottonseed oil, hydrogenated C<sub>12</sub>-C<sub>18</sub> triglycerides, hydrogenated fish oil, hydrogenated lard, hydrogenated menhaden oil, hydrogenated mink oil, hydrogenated orange roughy oil, hydrogenated palm kernel oil, hydrogenated palm oil, hydrogenated peanut oil, hydrogenated shark liver oil, hydrogenated soybean oil, hydrogenated tallow, hydrogenated vegetable oil, lard, lauric/palmitic/oleic triglyceride, lesquerella oil, linseed oil, macadamia nut oil, maleated soybean oil, meadowfoam seed oil, menhaden oil, mink oil, moringa oil, mortierella oil, neatsfoot oil, oleic/linoleic triglyceride, oleic/palmitic/lauric/myristic/linoleic triglyceride, oleostearine, olive husk oil, olive oil, omental lipids, orange roughy oil, palm kernel oil, palm oil, peach kernel oil, peanut oil, pengawar djambi oil, pentadesma butter, phospholipids, pistachio nut oil, placental lipids, rapeseed oil, rice bran oil, safflower oil, sesame oil, shark liver oil, shea butter, soybean oil, sphingolipids, sunflower seed oil, sweet almond oil, tall oil, tallow, tribehenin, tricaprin, tricaprylin, triheptanoin, trihydroxymethoxystearin, trihydroxystearin, triisononanoin, triisostearin, trilaurin, trilinolein, trilinolenin, trimyristin, trioctanoin, triolein, tripalmitin, trisebacin, tristearin, triundecanoin, vegetable oil, walnut oil, wheat bran lipids, wheat germ oil, and zadoary oil.

When the moisturizing and lubricating compositions of the present invention comprise a skin enhancing agent such as a fat or oil described above, it is highly preferred that the composition also comprise an antioxidant. Compositions suitable for use on absorbent products such as interlabial pads that contain a fat or oil skin enhancing agent without

an antioxidant tend to develop an offensive odor making the product commercially unsuitable. This problem is especially acute when the products are exposed to elevated temperatures during processing, storage and shipping. It has been  
5 discovered that the offensive odor is attributable to the partial or complete oxidation of the fat or oil. As such, by introducing an antioxidant into the moisturizing and lubricating compositions of the present invention, the development of an offensive odor over time can be  
10 substantially minimized or eliminated resulting in a substantially improved commercial product.

In addition to minimizing or eliminating offensive odors which can be produced by natural fats or oils comprising the moisturizing and lubricating compositions of the present  
15 invention, the antioxidant may provide a skin health benefit by repairing damaged lipids on the skin's surface. The epidermal lipids consist of a high proportion of polyunsaturated fatty acids, which are susceptible to oxidation on the skin's surface. Oxidation of these  
20 polyunsaturated fatty acids can be initiated by a number of means including metals, such as iron, which are naturally present in the skin as well as in menstrual fluid. Antioxidants can prevent or repair oxidative damage to polyunsaturated fatty acids as well as other oxidation prone  
25 constituents in the skin.

The antioxidant is present in the moisturizing and lubricating compositions of the present invention in an amount of from about 0.05% (by weight) to about 5% (by weight), preferably from about 0.1% (by weight) to about 2%  
30 (by weight), and more preferably from about 0.1% (by weight) to about 1% (by weight). Antioxidants suitable for reducing the likelihood of the fats and/or oils to oxidize on the bodyfacing surface of the interlabial pad and produce an unwanted odor include natural and synthetic tocopherol,  
35 butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol,

sodium sulfite, grape seed extract, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, avocado, sage, and proanthrocyanidins. Particularly preferred antioxidants include natural and synthetic  
5 tocopherol, BHT, and gamma oryzanol. Synthetic tocopherols include, for example tocopherol acetate, tocopherol linoleate, tocopherol succinate, tocopherol sorbate, tocotrienol, and Trolox (6-hydroxy-2, 5, 7, 8-tetramethyl chromane-2carboxylic acid).

10 The moisturizing and lubricating compositions of the present invention may also optionally include a sterol or sterol derivative or mixture of sterols and sterol derivatives to provide a skin health benefit. Typically, the moisturizing and lubricating compositions may include from  
15 about 0.1% (by weight) to about 10% (by weight), preferably from about 0.5% (by weight) to about 5% (by weight) and more preferably about 1% (by weight) of sterol or sterol derivative. Suitable sterols and sterol derivatives for incorporation into the moisturizing and lubricating  
20 compositions of the present invention include, for example, beta-sterols having a tail on the 17 position and having no polar groups, for example cholesterol, sitosterol, stigmasterol, and ergosterol, as well as C<sub>10</sub>-C<sub>30</sub> cholesterol/lanosterol esters, cholecalciferol, cholesteryl  
25 hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dihydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado  
30 sterols, cholesterol esters, sterol esters, and the like, as well as mixtures thereof.

The moisturizing and lubricating compositions of the present invention may also optionally include other components such as emulsifiers, surfactants, water, viscosity  
35 modifiers, pH modifiers, buffers, perfumes, antibacterial actives, antifungal actives, pharmaceutical actives, film

formers, deodorants, opacifiers, astringents, solvents, organic acids, preservatives, anti-viral actives, drugs, vitamins, aloe vera, panthenol, and the like. These materials are known in the art and are used in their art-established manner at their art-established amounts.

The moisturizing and lubricating compositions of the present invention are introduced onto the desired product in an amount sufficient to provide a moisturizing and lubricating benefit. For example, the moisturizing and lubricating compositions of the present invention may be introduced onto the bodyfacing surface of an interlabial pad in an amount of from about 0.05 g/m<sup>2</sup> to about 100 g/m<sup>2</sup>, more preferably from about 1.0 g/m<sup>2</sup> to about 40 g/m<sup>2</sup>, and even more preferably from about 4 g/m<sup>2</sup> to about 10g/m<sup>2</sup>. One particularly suitable amount of lubricating and moisturizing composition for application to the bodyfacing surface of an interlabial pad is about 6 g/m<sup>2</sup>.

The present invention is illustrated by the following Examples, which are not meant to be limiting in any manner.

#### EXAMPLE 1

In this Example two potential moisturizing and lubricating compositions were evaluated for their ability to provide for improved softness in a cover material suitable for use on the bodyfacing surface of an interlabial pad or other absorbent device by measuring their ability to provide initial and immediate skin moisturization on the forearm of a female test subject. The first moisturizing and lubricating composition tested was hydrophilic in nature, and the second was hydrophobic in nature. The hydrophilicity and hydrophobicity of the compositions were measured by their solubility in water at 80°C, as discussed above. The hydrophilic composition was approximately 48% soluble and the hydrophobic composition was approximately 10% soluble. Conductance and capacitance readings were taken after skin

contact with the test compositions for five minutes, fifteen minutes, and sixty minutes.

The hydrophobic test composition was comprised as shown in Table 1, and the hydrophilic test composition was

5 comprised as shown in Table 2:

Table 1: Hydrophobic

| Component                       | Weight Percent |
|---------------------------------|----------------|
| Glycerin (Glenn Corp.)          | 10             |
| Prolipid 141 (ISP)              | 1              |
| Soya Sterol (Cognis/Henkel)     | 1              |
| Sunflower Oil (Cargil)          | 10             |
| Ozokerite Wax (Allyson AE-1692) | 30             |
| Petrolatum (Ultra Chemical)     | 46             |
| Silica (Cabot)                  | 2              |

Table 2: Hydrophilic

| Component   | Weight Percent |
|---|----------------|
| Glycerin (Glenn Corp.)  | 10             |
| Propylene Glycol (Glenn Corp.)  | 28             |
| Dow Corning® 1403 Fluid<br>(Dimethiconol and Dimethicone) (Dow Corning) | 5              |
| Dow Corning® 200 Fluid, 100<br>Centistokes (Dimethicone) (Dow Corning)  | 5              |
| Prolipid 141 (ISP)  | 1              |
| Soya Sterol (Cognis Henkel)   | 1              |
| Sunflower Oil (Cargil)  | 10             |
| Polyethylene Glycol 8000 (Union Carbide)                                | 20             |
| Behenyl Alcohol (Glenn Corp)  | 10             |
| Stearyl Alcohol (Glenn Corp)  | 10             |

10

Twenty female volunteers were brought into an environmentally controlled room (70°F  $\pm$  3°F and 45% relative humidity  $\pm$  5%) for fifteen minutes to allow for equilibration. This allowed for the skin of the volunteers



to equilibrate with the test environment (come to a constant temperature and moisture level). Test sites, which were 2.5 centimeters by 2.5 centimeters, on the volar aspect of the test subject's forearms were marked with a surgical skin marker to ensure formulation application and subsequent skin measurements were performed at the same sites.

After equilibration, approximately 6 g/m<sup>2</sup> of either the hydrophilic or hydrophobic test formulation was applied to randomly assigned test sites with a positive displacement pipette, and rubbed over the area using a finger cot. Capacitance readings, which were calculated by averaging three 5-second readings, were taken using a Novameter capacitance measurer (NOVA DPM 9003a; Nova Technology Corporation, Portsmouth, NH.) Conductance readings, which were calculated by averaging three 5-second readings, were taken using a Skicon conductance measurer (Skicon I.B.S., Hamamatsu-shi, Japan). Both instruments provided a reading that is expressed in arbitrary units (AU). Untreated volar forearm areas were also measured as controls. Both sets of capacitance and conductance data were analyzed using Analysis of Variance techniques known in the art after five minutes, fifteen minutes, and sixty minutes. A higher capacitance value (Novameter) meant that the skin was more conductive and thus had higher moisture content. Similarly, a higher conductance value (Skicon) was also indicative of higher skin moisture content. The results are shown in Table 3 (Novameter Capacitance Data (AU)) and Table 4 (Skicon Conductance Data (AU)).

Table 3: (Novameter Capacitance Data (AU))

| Composition         | 5 Minutes | 15 Minutes | 60 Minutes |
|---------------------|-----------|------------|------------|
| Hydrophilic         | 149.3*    | 149.3*     | 105.9*     |
| Hydrophobic         | 95.3      | 98.1       | 98.2       |
| Control (untreated) | 95.1      | 97.1       | 96.3       |

\*Significantly higher than the control site ( $p \leq 0.01$ )

Table 4: (Skicon Capacitance Data (AU))

| Composition            | 5 Minutes | 15 Minutes | 60 Minutes |
|------------------------|-----------|------------|------------|
| Hydrophilic            | 347.4*    | 261.3      | 186.9      |
| Hydrophobic            | 217.0     | 195.8      | 209.1      |
| Control<br>(untreated) | 234.4     | 254.5      | 245.0      |

5 \*Significantly higher than the control site ( $P \leq 0.01$ )

As the data in Table 3 indicate, the hydrophilic composition resulted in significantly higher initial moisturization of the skin at all time points measured while the hydrophobic composition did not result in any significant moisturization at any time measurement. This indicates that the hydrophilic composition is significantly more effective in moisturizing the skin immediately upon application than the hydrophobic composition, especially at the initial 5 and 15 minute measurements. The immediate moisturizing effect of the hydrophilic composition allows for greater ease and comfort in inserting the interlabial pad.

As the data in Table 4 indicate, the hydrophilic composition again resulted in more skin moisturization at the 5 time point whereas again, the hydrophobic composition did not provide a detectable effect.

Both sets of data indicate that the hydrophilic composition adds significant moisture to the skin immediately upon application. This is important due to the important need for moisturization of interlabial skin immediately upon insertion and use of the interlabial device. Typically, moisturization of the labial area becomes less important with time as the undesirable sensation of interlabial dryness dissipates due to the accumulation of fluid in the product as the product is worn. As such, a protracted delivery of a moisturizer may not be necessary to improve the comfort and

overall consumer acceptance of the interlabial absorbent product.

#### EXAMPLE 2

5           In this example four substrates intended for use as the bodyfacing surface of an interlabial pad or other absorbent product treated with the moisturizing and lubricating hydrophilic composition from example 1 were evaluated for their ability to provide for improved skin barrier integrity  
10 by measuring their ability to provide skin moisturization, no damage to the skin's natural barrier function and reduce skin irritation when repetitively wiped on the volar forearm. The first moisturizing and lubricating substrate treated for testing was polypropylene thermally bonded carded web (TBCW)  
15 treated with approximately 6g/m<sup>2</sup> of the hydrophilic formulation of Example 1. The second substrate was polypropylene thermally bonded carded web (TBCW) treated with approximately 10g/m<sup>2</sup> of hydrophilic formulation. The third substrate tested was 80/20 bicomponent/rayon fiber TBCW  
20 treated with approximately 6g/m<sup>2</sup> of hydrophilic formulation, and the fourth was 90/10 TBCW treated with approximately 6g/m<sup>2</sup> of hydrophilic formulation. An untreated substrate, a non-woven material, was used as the control. The treated substrates had the compositions applied thereon by a slot-coating process.  
25

Due to the fact that physical activity, or any sort of stimulus, has been shown to increase TEWL values, the thirty-three female volunteers were brought into an environmentally controlled room (70°F  $\pm$  3°F and 45% relative humidity  $\pm$  5%)  
30 for fifteen minutes to allow for equilibration. The right and left volar forearms were independently marked in up to three sites using a surgical marker. The sites (2.5 centimeters X 2.5 centimeters) were randomly assigned treated or untreated test substrates. Baseline measurements were  
35 taken for TEWL using a TEWL meter. Capacitance readings were taken using a Novameter Capacitance measurer as described in

Example 1. Erythema was assessed by trained expert graders using a Visual Grading scale, which is well known in the art and represented in Table 5.

Table 5:

| Score | Redness Evaluation                |
|-------|-----------------------------------|
| 0     | No observable redness             |
| 1     | Slight redness, spotty or diffuse |
| 2     | Moderate redness                  |
| 3     | Intense redness                   |
| 4     | Fiery red with edema              |

5

Each forearm site was wiped with its designated substrate 20 times (one wiping cycle). Wiping was accomplished with the aid of a backing material (2.5 centimeters by 2.5 centimeter piece of 50% cotton/50% rayon absorbent material) placed behind the test substrate to afford additional integrity for the very low basis weight cover materials and to simulate the bulk of the absorbent core of an interlabial device. After a wiping cycle, a semi-occlusive patch (Scanpore® tape with a cotton center available from Bard Medical; Covington, Georgia) was applied over each site. The wiping was repeated for 24 wiping cycles for a total of 480 wipes. A new substrate was used for each wiping cycle. Additional TEWL, capacitance, and erythema readings were taken after wiping cycles 6, 12, 18, and 24. Following the readings, the testing sites were re-patched semi-occlusively as before. The results for capacitance as measured by the Novameter are shown in Table 6A.

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15

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Table 6A: Skin moisture levels as measure by Novameter

| Substrate  | Baseline | Post cycle 1 | Post cycle 6 | Post cycle 12 | Post cycle 18 | Post cycle 24 |
|--|----------|--------------|--------------|---------------|---------------|---------------|
| Polypropylene TBCW with 6g/m <sup>2</sup> of formulation | 106.6    | 112.7*       | 129.3*       | 147.3*        | 152.1*        | 161.8*        |
| Polypropylene  | 107.4    | 112.3*       | 120.4*       | 130.4*        | 131.1*        | 135.6*        |

|  |       |        |        |        |        |        |
|--|-------|--------|--------|--------|--------|--------|
| TBCW with<br>10g/m <sup>2</sup> of<br>formulation                              |       |        |        |        |        |        |
| 90/10<br>bicomponent/rayon<br>TBCW with<br>6g/m <sup>2</sup> of<br>formulation | 107.0 | 108.4  | 113.7  | 115.9  | 114.9  | 116.5  |
| 80/20 bicomponent<br>fiber TBCW<br>6g/m <sup>2</sup> of<br>formulation         | 108.5 | 111.9* | 121.0* | 126.4* | 132.4* | 135.6* |
| Untreated<br>Sandler (4346<br>Sawabond)  | 107.7 | 108.9  | 113.3  | 111.7  | 114.4  | 115.4  |
| Untreated<br>Skin/control  | 106.7 | 107.3  | 108.1  | 110.9  | 109.6  | 111.9  |

\*Value is significantly higher than untreated control value  
( $p \leq 0.01$ )

The data of Table 6A indicated that polypropylene TBCW  
5 treated with 6g/m<sup>2</sup> of formulation moisturized the skin  
significantly better than the untreated control material and  
control. Both polypropylene TBCW treated with 10g/m<sup>2</sup> of  
formulation and 80/20 bicomponent/rayon fiber TBCW treated  
10 with 6g/m<sup>2</sup> of formulation were found to impart skin  
moisturization. Both the 90/10 TBCW treated with 6g/m<sup>2</sup> of  
formulation and the untreated Sandler did not provide  
detectable moisturization.

The results of the TEWL meter indicated that there was  
no effect on transepidermal water loss and thus no damage to  
15 the skin's natural barrier function. (See Table 6B).  
Repetitive wiping of the skin can damage the skin's barrier  
function thereby elevating TEWL and may also result in a  
concomitant increase in skin (stratum corneum) moisture  
levels. If skin barrier damage occurred it may be difficult  
20 to ascribe increased conductance and/or capacitance readings  
solely to the moisturization effect of the compositions being  
evaluated. The contribution of water content in the stratum

corneum due to the skincare composition may be confounded by that present due to skin damage, making the interpretation of the data more difficult. To account for this possibility, TEWL was measured in this Example to ensure that the moisturizing effect of the formulation was not a result of damage to the skin barrier due to repetitive wiping. The results indicate that TEWL did not change over the course of the wiping cycles. This finding confirms that the moisturizing benefit can be ascribed to the moisturizing composition rather than to skin damage. The results of the erythema readings remained zero for all measurements at all wiping cycles indicating no skin irritation was caused by the treated substrates.

Table 6B: TEWL Values

| Substrate  | Baseline | Post cycle 1 | Post cycle 6 | Post cycle 12 | Post cycle 18 | Post cycle 24 |
|--|----------|--------------|--------------|---------------|---------------|---------------|
| Polypropylene TBCW with 6g/m <sup>2</sup> of formulation       | 4.21     | 4.08         | 3.66         | 4.03          | 4.25          | 4.21          |
| Polypropylene TBCW with 10g/m <sup>2</sup> of formulation      | 4.19     | 4.22         | 3.64         | 3.92          | 4.05          | 4.02          |
| 90/10 bicomprayon TBCW with 6g/m <sup>2</sup> of formulation   | 3.96     | 3.93         | 3.52         | 3.86          | 4.25          | 4.20          |
| 80/20 bicompr fiber TBCW with 6g/m <sup>2</sup> of formulation | 4.25     | 4.15         | 3.76         | 3.88          | 4.29          | 4.10          |
| Untreated Sandler (4346 Sawabond)                              | 4.29     | 4.04         | 3.75         | 4.41          | 4.56          | 4.60          |
| Untreated Skin/ Control  | 4.09     | 3.96         | 3.73         | 4.02          | 4.50          | 4.19          |

EXAMPLE 3

In this example, three substrates intended for use as the bodyfacing surface of an interlabial pad treated with moisturizing and lubricating hydrophilic compositions were evaluated for their ability to provide for improved skin barrier integrity by measuring their ability to provide skin moisturization, no damage to the skin's natural barrier function and reduced skin irritation when repetitively wiped in the nasolabial fold. The first substrate is polypropylene TBCW treated with the hydrophilic formulation from example 1 and the second is 80/20 bicomponent/bicomponent TBCW treated with the hydrophilic formulation. Again, an untreated Sandler was used as a control.

To ensure that the skin was free of make up and moisturizes, forty-eight female volunteers were directed to wash their face at home with their usual soap or cleanser one to two hours prior to testing time. They were then brought into an environmentally controlled room ( $70^{\circ}\text{F} \pm 3^{\circ}\text{F}$  and  $45\%$  relative humidity  $\pm 5\%$ ) for twenty minutes to acclimate. Using a surgical pen, one test site (approximately 2.5 centimeter X 2.5 centimeter) on each side of the nose between the nasolabial fold and the bottom of the left and right sides of the nose was marked with a randomized test code. The volunteer was told to rest back in a chair until the nasolabial area was as horizontal to the floor as possible.

TEWL baseline readings were taken using a Dermalab evaporimeter.

DERMALAB EVAPORIMETER TEST:

Step 1: The Dermalab Evaporimeter (CyberDerm, Medina, PA) was placed on the left testing site of the nose.

Step 2: The TEWL reading was collected for one minute.

Step 3: This process was repeated on the right testing side of the nose.

Baseline readings for capacitance were taken on the left and right testing sites using a Novameter (NOVA DPM 9003a (Nova Technologies, Gloucester, MA)).

5       The left testing site was then manually wiped using a new piece of liner material (3" X 2") with the hydrophilic formulation side toward the skin supported by a precut backing material (1.5" X 2" piece of 50% cotton/50% rayon absorbent material) placed behind the test substrate to  
10 afford additional integrity for the very low basis weight cover materials and to simulate the bulk of the absorbent core of an interlabial device. The site was wiped ten times. A new liner and backing material were then again wiped down the same testing site ten more times for a total of twenty  
15 wipes (one wiping cycle). This procedure was repeated every ten minutes for a total of twelve wiping cycles. The entire procedure was repeated on the right side of the nose with the appropriate code material.

20       Readings for TEWL and capacitance were taken after cycles 3, 6, 9, and 12 with a twenty minute waiting period in between. The results are shown in Table 7 (TEWL readings taken by Dermalab evaporimeter ) and Table 8 (capacitance readings taken by Novameter):

25   Table 7:

| Substrate                               | Baseline<br>0 | Post Cycle<br>3 | Post Cycle<br>6 | Post Cycle<br>9 | Post<br>Cycle 12 |
|---|---------------|-----------------|-----------------|-----------------|------------------|
| Polypropylene<br>TBCW                   | 22.20         | 22.53           | 21.74           | 21.88           | 21.21*           |
| 80/20<br>bicom/bicom<br>TBCW            | 21.78         | 22.77           | 22.12           | 22.42           | 22.23            |
| Untreated<br>Sandler (4346<br>Sawabond) | 21.76         | 22.17           | 22.89           | 23.24           | 23.54*           |

\* Indicates significant differences



Table 8: (Natural Logs of Novameter Data)

| Substrate                               | Baseline<br>0 | Post Cycle<br>3 | Post Cycle<br>6 | Post Cycle<br>9 | Post<br>Cycle 12 |
|---|---------------|-----------------|-----------------|-----------------|------------------|
| Polypropylene<br>TBCW                   | 4.77          | 5.12*           | 5.19*           | 5.31*           | 5.37*            |
| 80/20<br>bicomp/bicomp<br>TBCW          | 4.79          | 5.12*           | 5.26*           | 5.36*           | 5.42*            |
| Untreated<br>Sandler (4346<br>Sawabond) | 4.79          | 4.89            | 4.96            | 4.98            | 5.02             |

\* Indicates significant differences

The data in Table 7 indicated that neither treated materials caused damage to the skin barrier, as the TEWL readings remained low. Polypropylene TBCW had significantly lower TEWL readings indicating more gentleness. The untreated Sandler substrate caused small but significant barrier damage by cycle 12.

The data in Table 8 indicated that both polypropylene TBCW and 80/20 bicomponent/bicomponent TBCW treated with the hydrophilic formulation significantly moisturized the skin compared to the untreated Sandler control over the whole study.

In view of the above, it will be seen that the several objects of the invention are achieved. As various changes could be made in the above-described products and methods without departing from the scope of the invention, it is intended that all matter contained in the above description be interpreted as illustrative and not in a limiting sense.

WHAT IS CLAIMED IS:

1. A moisturizing and lubrication composition comprising from about 5% (by weight) to about 90% (by weight) of a humectant, from about 1% (by weight) to about 25% (by weight) of an emollient, from about 0.1% (by weight) to about 30% (by weight) of a fat or oil skin barrier enhancing agent, and from about 10% (by weight) to about 90% (by weight) of an immobilizing agent.
2. The moisturizing and lubricating composition as set forth in claim 1 further comprising from about 0.05% (by weight) to about 5% (by weight) antioxidant.
3. The moisturizing and lubricating composition as set forth in claim 1 further comprising from about 0.1% (by weight) to about 2% (by weight) antioxidant.
4. The moisturizing and lubricating composition as set forth in claim 1 further comprising from about 0.1% (by weight) to about 1% (by weight) antioxidant.
5. The moisturizing and lubricating composition as set forth in claim 1 wherein the composition is hydrophilic.
6. The moisturizing and lubricating composition as set forth in claim 1 wherein the composition is at least about 45% soluble in deionized water at a temperature of about 80°C.
7. The moisturizing and lubricating composition as set forth in claim 1 wherein the composition is at least about 60% soluble in deionized water at a temperature of about 80°C.

8. The moisturizing and lubricating composition as set forth in claim 1 wherein the composition is at least about 80% soluble in deionized water at a temperature of about 80°C.

9. The moisturizing and lubricating composition as set forth in claim 1 wherein the composition has a melting point of from about 30°C to about 80°C.

10. The moisturizing and lubricating composition as set forth in claim 1 wherein the composition has a melting point of from about 55°C to about 65°C.

11. The moisturizing and lubricating composition as set forth in claim 1 wherein the composition has a melting point of from about 60°C to about 62°C.

12. The moisturizing and lubricating composition as set forth in claim 1 wherein the composition is capable of freezing on a substrate in from about 0.25 seconds to about 3 seconds.

13. The moisturizing and lubricating composition as set forth in claim 1 wherein the composition has a penetration hardness of from about 5 millimeters to about 360 millimeters.

14. The moisturizing and lubricating composition as set forth in claim 1 wherein the composition has a penetration hardness of from about 10 millimeters to about 120 millimeters.

15. The moisturizing and lubricating composition as set forth in claim 1 wherein the composition has a penetration hardness of from about 20 millimeters to about 100 millimeters.

16. The moisturizing and lubricating composition as set forth in claim 1 wherein the humectant is selected from the group consisting of acetamide MEA, aloe vera gel, arginine PCA, chitosan PCA, copper PCA, corn glycerides, dimethyl  
5 imidazolidinone, fructose, glucamine, glucose, glucose glutamate, glucuronic acid, glutamic acid, glycereth-7, glycereth-12, glycereth-20, glycereth-26, glycerin, honey, hydrogenated honey, hydrogenated starch hydrolysates, hydrolyzed corn starch, lactamide MEA, lactic acid, lactose  
10 lysine PCA, mannitol, methyl gluceth-10, methyl gluceth-20, PCA, PEG-2 lactamide, PEG-10 propylene glycol, polyamino sugar condensate, potassium PCA, propylene glycol, propylene glycol citrate, polyamino acid, polysaccharide, saccharide hydrolysate, saccharide isomerate, sodium aspartate, sodium  
15 lactate, sodium PCA, sorbitol, TEA-lactate, TEA-PCA, Urea, Xylitol, and mixtures thereof.

17. The moisturizing and lubricating composition as set forth in claim 1 wherein the humectant is selected from the group consisting of polyols, glycerine, ethoxylated glycerine, polyethylene glycols, hydrogenated starch  
5 hydrolysates, propylene glycol, silicone glycol, pyrrolidone carboxylic acid, and mixtures thereof.

18. The moisturizing and lubricating composition as set forth in claim 1 wherein the humectant is selected from the group consisting of glycerin, polyethylene glycol, propylene glycol, and mixtures thereof.

19. The moisturizing and lubricating composition as set forth in claim 1 wherein the emollient is selected from the group of petroleum based emollients, fatty acid esters, alkyl ethoxylates, fatty alcohols, silicones, and mixtures thereof.

20. The moisturizing and lubricating composition as set forth in claim 19 wherein the silicones are selected from the group consisting of dimethicone, dimethiconol, polyethylene glycol dimethicone, alkyl silicone, phenyl silicones,  
5 silicone phospholipids, and mixtures thereof.

21. The moisturizing and lubricating composition as set forth in claim 1 wherein the immobilizing agent is selected from the group consisting of C<sub>14</sub>-C<sub>22</sub> fatty alcohols, C<sub>12</sub>-C<sub>22</sub> fatty acids, solid fatty acid esters, C<sub>12</sub>-C<sub>22</sub> fatty alcohol  
5 ethoxylates having an average degree of ethoxylation ranging from about 2 to about 30, high molecular weight polyethylene glycols, and mixtures thereof.

22. The moisturizing and lubrication composition as set forth in claim 21 wherein the high molecular weight polyethylene glycols have an average degree of ethoxylation of from about 18 to about 160,000.

23. The moisturizing and lubrication composition as set forth in claim 21 wherein the high molecular weight polyethylene glycols have an average degree of ethoxylation of from about 135 to about 45,000.

24. The moisturizing and lubrication composition as set forth in claim 21 wherein the high molecular weight polyethylene glycols have an average degree of ethoxylation of about 10,000.

25. The moisturizing and lubricating composition as set forth in claim 1 wherein the skin barrier enhancing agent is present in an amount of from about 0.5% (by weight) to about 20% (by weight).

26. The moisturizing and lubricating composition as set forth in claim 1 wherein the skin barrier enhancing agent is

present in an amount of from about 1% (by weight) to about 10% (by weight).

27. The moisturizing and lubricating composition as set forth in claim 1 wherein the skin barrier enhancing agent is selected from the group consisting of natural fats and oils, glycerides, triglycerides, essential fatty acids, non-essential fatty acids, sphingolipids, and mixtures thereof.

28. The moisturizing and lubricating composition as set forth in claim 1 wherein the skin barrier enhancing agent is selected from the group consisting of apricot kernel oil, avocado oil, babassu oil, borage seed oil, butter, C<sub>12</sub>-C<sub>18</sub> acid triglyceride, camellia oil, canola oil, caprylic/capric/lauric triglyceride, caprylic/capric/linoleic triglyceride, caprylic/capric/stearic triglyceride, caprylic/capric triglyceride, carrot oil, cashew nut oil, castor oil, cherry pit oil, chia oil, cocoa butter, coconut oil, cod liver oil, corn germ oil, corn oil, cottonseed oil, C<sub>10</sub>-C<sub>18</sub> triglycerides, egg oil, epoxidized soybean oil, evening primrose oil, glyceryl triacetyl hydroxystearate, glyceryl triacetyl ricinoleate, glycosphingolipids, grape seed oil, hazelnut oil, human placental lipids, hybrid safflower oil, hybrid sunflower seed oil, hydrogenated castor oil, hydrogenated castor oil laurate, hydrogenated coconut oil, hydrogenated cottonseed oil, hydrogenated C<sub>12</sub>-C<sub>18</sub> triglycerides, hydrogenated fish oil, hydrogenated lard, hydrogenated menhaden oil, hydrogenated mink oil, hydrogenated orange roughy oil, hydrogenated palm kernel oil, hydrogenated palm oil, hydrogenated peanut oil, hydrogenated shark liver oil, hydrogenated soybean oil, hydrogenated tallow, hydrogenated vegetable oil, lard, lauric/palmitic/oleic triglyceride, lesquerella oil, linseed oil, macadamia nut oil, maleated soybean oil, meadowfoam seed oil, menhaden oil, mink oil, moringa oil, mortierella oil, neatsfoot oil, oleic/linoleic triglyceride,

oleic/palmitic/lauric/myristic/linoleic triglyceride,  
oleostearine, olive husk oil, olive oil, omental lipids,  
30 orange roughy oil, palm kernel oil, palm oil, peach kernel  
oil, peanut oil, pengawar djambi oil, pentadesma butter,  
phospholipids, pistachio nut oil, placental lipids, rapeseed  
oil, rice bran oil, safflower oil, sesame oil, shark liver  
oil, shea butter, soybean oil, sphingolipids, sunflower seed  
35 oil, sweet almond oil, tall oil, tallow, tribehenin,  
tricaprin, tricaprylin, triheptanoin,  
trihydroxymethoxystearin, trihydroxystearin, triisononanoin,  
triisostearin, trilaurin, trilinolein, trilinolenin,  
trimyristin, trioctanoin, triolein, tripalmitin, trisebacin,  
40 tristearin, triundecanoin, vegetable oil, walnut oil, wheat  
bran lipids, wheat germ oil, zadoary oil, and mixtures  
thereof.

29. The moisturizing and lubricating composition as set  
forth in claim 2 wherein the antioxidant is selected from the  
group consisting of natural and synthetic tocopherol,  
butylated hydroxyanisole (BHA), butylated hydroxytoluene  
5 (BHT), carotenoids, filtered wheat germ oil, gamma oryzanol,  
sodium sulfite, grape seed extract, green tea extract,  
rosmaric acid, ubiquinone, lipoic acid, N-acetyl-cysteine,  
avocado, sage, proanthrocyanidins, and mixtures thereof.

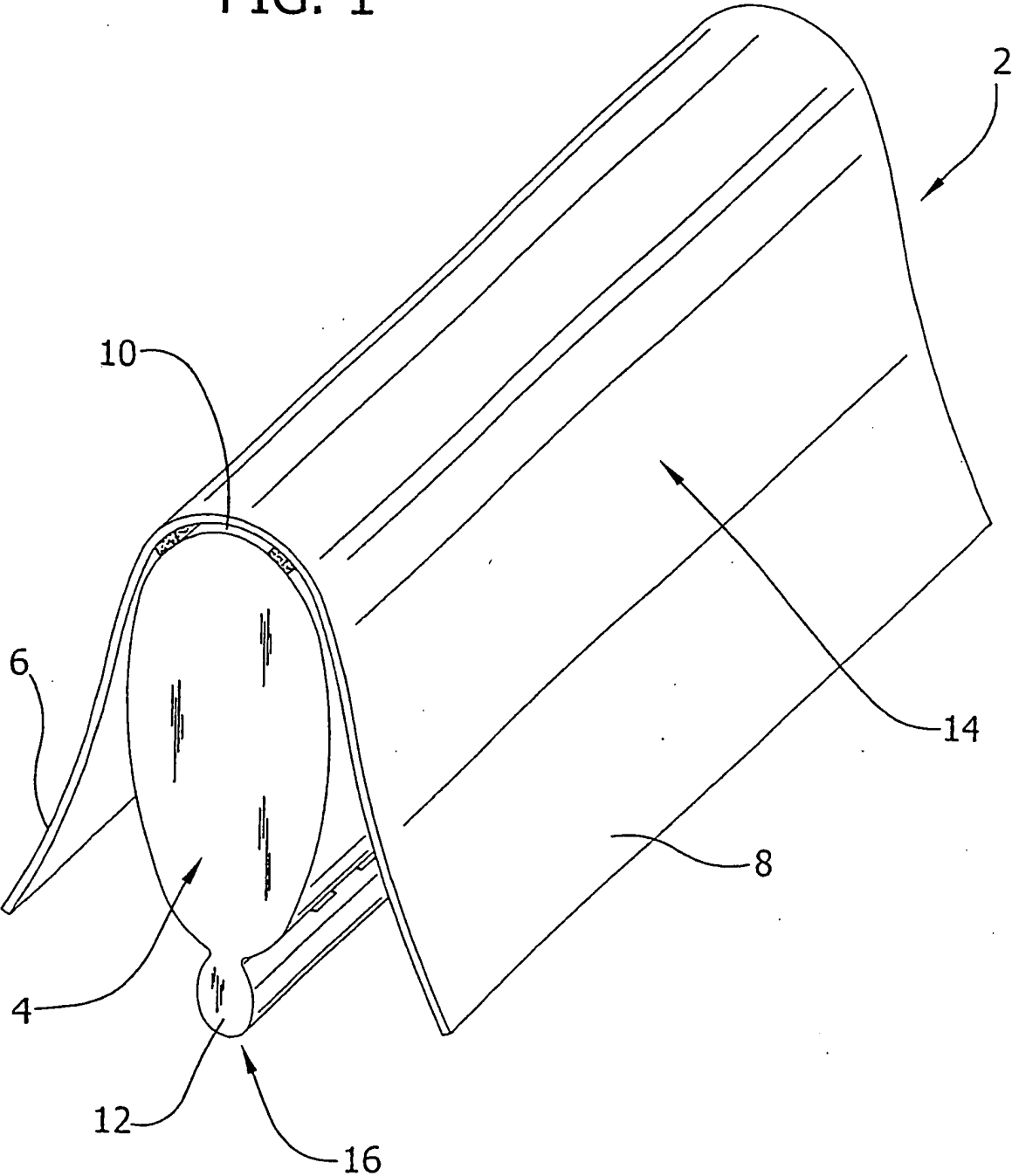
30. The moisturizing and lubricating composition as set  
forth in claim 2 wherein the antioxidant is selected from the  
group consisting of natural and synthetic tocopherol,  
butylated hydroxytoluene, gamma oryzanol, and mixtures  
5 thereof.

31. The moisturizing and lubricating composition as set  
forth in claim 1 further comprising one or more of components  
selected from the group consisting of emulsifiers,  
surfactants, water, viscosity modifiers, pH modifiers,  
5 buffers, perfumes, antibacterial actives, antifungal actives,

pharmaceutical actives, film formers, deodorants, opacifiers, astringents, solvents, organic acids, preservatives, anti-viral actives, drugs, vitamins, aloe vera, and panthenol.



FIG. 1



## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/25643

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61L15/42

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61L A61F A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
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☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

19 December 2003

Date of mailing of the international search report

07/01/2004

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